K070333
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510(k) Summary

Contact Person: Bruce L. Gibbins, PhD

Date of preparation: January 26, 2007

JUL 10 2007

Device Name (proprietary): AcryDerm OTC Silver Antimicrobial Wound Gel

Common Name: Moist antimicrobial wound filler

Classification Name: Hydrophilic wound dressing

Classification: Unclassified

Legally marketed device(s) for substantial equivalence comparison:

AcryDerm Silver Antimicrobial Wound Gel (AcryMed, Inc., OR)

SilverMed Antimicrobial Silver Hydrogel (Argentis Biomedical, Tx)

Silver Shield Antimicrobial Skin and Wound Gel (Anacapa Tech., Inc., Ca)

Description of Device: AcryDerm Silver Antimicrobial OTC Wound Gel is a moist amorphous gel wound filler that contains antimicrobial silver. It is supplied in collapsible blind ended heat sealed co-laminate tubes fitted with screw caps.

Intended Use of the Device: AcryDerm Silver Antimicrobial OTC Wound Gel is intended for use on intact and broken skin and dermal injuries such as minor laceration, cuts, burns, scrap and minor surgical procedures.

Technological Characteristics: AcryDerm Silver Antimicrobial OTC Wound Gel is a repeat-use antimicrobial barrier amorphous gel wound cover that contains ionic silver. Antimicrobial barrier activity has been demonstrated by Kirby-Bauer zone of inhibition assays against a broad spectrum of bacteria and fungi including: *Staphylococcus epidermitis, E. coli, Pseudomonas aeruginosa, Staphylococcus aureus (*MRSA), *Candida albicans,* and *Enterococcus faecium, Klebsiella pneumoniae* (3 strains), *Candida parapsilosis, Candida galbrata , Bacillus subtilis, Enterobacter cloacae* (2 strains), *Enterococcus faecalis* (2 strains), *Aspergillus niger, Serratia marcescens, Citrobacter diversus, Citrobacter kasseri, Staphylococcus saprophyticus, Epidermophyton sp., Microsporum sp., and Tricophyton sp.* The silver antimicrobial wound gel has been shown by in vitro serial transfer testing to maintain a barrier function for more than 3 days.

Manufacturing: AcryDerm Silver Antimicrobial OTC Wound Gel will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe, effective, and correctly labeled for its intended use.

Performance testing: The antimicrobial barrier activity of the new product has been established by the Kirby-Bauer zone of inhibition test. In addition, the new product conforms with the USP Preservative Challenge Test performed against the strains of organisms specified in the USP

Preservative Challenge Test protocol. Biocompatibility has been assessed according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

Purpose for this Submission

This application is being made in order to gain clearance to market a previously cleared product for Over The Counter (OTC) distribution. The product **AcryDerm Silver Antimicrobial Wound Gel** received clearance to market (K011994) and has been in continuous distribution since 2002 as a **prescription only** product. The complaint history, biocompatibility, safety, and performance in a wound healing study show that it would be safe for wider and more direct access of this product by patients. Clearance to OTC distribution is respectfully sought in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AcryMed, Inc.
% Bruce Gibbons, PhD
Chief Technology Officer
9560 SW Nimbus Avenue
Beaverton, Oregon 97008

JUL 10 2007

Re: K070333
Trade/Device Name: AcryDerm Silver Antimicrobial OTC Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 5, 2007
Received: June 20, 2007

Dear Dr. Gibbons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter Rumm

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DRP O.A 7/10/07

Enclosure

510(k) NUMBER (IF KNOWN): K070333

DEVICE NAME: AcryDerm Silver Antimicrobial OTC Wound Gel

INDICATIONS FOR USE:

AcryDerm Silver Antimicrobial OTC Wound Gel is intended for use on intact and broken skin and dermal injuries such as minor laceration, cuts, burns, scrapes and minor surgical procedures wounds.

Prescription use ___ (Per 21 CFR 801.109) OR Over-The-Counter-Use X (Optional Format 1)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070333